DRAFT FOR PUBLIC COMMENT
March 20, 2003

SUPPORTING STATEMENT FOR
AN INFORMATION COLLECTION REQUEST (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a). Title of the Information Collection

COMPLIANCE REQUIREMENT FOR CHILD-RESISTANT PACKAGING

OMB NO. 2070-0052
EPA NO. 0616.08

1(b). Short Characterization/Abstract

This information collection program is designed to provide the Environmental Protection Agency (EPA) with assurances that the packaging of pesticide products sold and distributed to the general public in the United States meets standards set forth by the Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Registrants must certify to the Agency that the packaging or device meets these standards. There are no forms associated with this information collection activity.

2. NEED FOR AND USE OF THE COLLECTION

2(a). Need/Authority for the Collection

Section 25 (c)(3) of FIFRA authorizes EPA to establish standards for packaging of pesticide products and pesticidal devices to protect children and adults from serious illness or injury resulting from accidental ingestion or contact (see attachment A). The law requires that these standards are designed to be consistent with those under the Poison Prevention Packaging Act, administered by the Consumer Product Safety Commission (CPSC). Unless a pesticide product qualifies for an exemption, the product meets certain criteria regarding toxicity and use, it must be sold and distributed in child-resistant packaging. The authority for this information collection is pursuant to Section 25 (c)(3) of the FIFRA. Compliance regulations are contained in 40 Code of Federal Regulations (CFR) Part 157.

2(b). Practical Utility/Users of the Data

EPA reviews a registrant's child-resistant packaging (CRP) certification to determine if there are human safety/health risk concerns. Exemption requests are reviewed to ascertain if there is a health risk, and if CRP is technically feasible, practicable, and appropriate.

3. NON DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a). Non duplication

Not applicable. The EPA's CRP regulations reference the CPSC packaging standards and protocol testing procedures for CRP to avoid duplicative testing of packages for pesticidal and non-pesticidal purposes. This is the only information collection activity of its kind and the information collected under this activity is collected only once per event (e.g., once per certification of CRP compliance).

3(b). Public Notice Required Prior to ICR Submission to OMB

Pursuant to 5 CFR 1320.8(d), EPA published a notice in the *Federal Register* on August 4, 1999 (64 FR 42365) soliciting comments on this information collection activity and the Agency's intent to renew the OMB approval of the ICR. EPA received no comments in response to that notice.

3(c). Consultations

The CPSC is consulted by EPA on general packaging issues, products under joint jurisdiction (e.g. bleaches and pine oil products), and the regulatory aspect of implementing consumer (child) safety measures in a way that keeps them consistent with those under the Poison Prevention Packaging Act.

Specific packaging issues (for example, determining what can reasonably be required or expected in terms of technical and/or economic feasibility) are discussed with the CPSC and the packaging industry itself. These consultations occur on an informal "as needed" basis during the process of evaluating exemption requests and certifying to the use of CRP. In the past, when any sort of problem (technical, administrative, or other) arose, or there were suggestions for improvement in the program, the respondent is given ample opportunity to inform the agency and vice versa. This communication between both parties may take place either in a telephone conversation or in a meeting setting, but not necessarily by a prescribed schedule.

3(d). Effects of Less Frequent Collection

Not applicable. The information collection occurs only once for each product package combination subject by law to the CRP provisions. In the absence of this information collection activity, the burden of proof would be shifted from the registrant to the EPA. Based on enforcement case precedents involving CRP, EPA would need to have specific evidence to make the product-package case. Consequently, on the basis of the time and cost involved, EPA would find it difficult to fulfill its statutory responsibilities to ensure that pesticides, are equipped with

protective packages adequate to protect children from accidental illness or injury.

3(e). General Guidelines

The only PRA-imposed guideline in 5 CFR 1320.6 that is exceeded in this collection is the recordkeeping retention period. Registrants or applicants of pesticides for which CRP is required must retain the records required under 40 CFR 157.36 for as long as the registration is valid.

Registrations are valid unless or until they are either voluntarily canceled or withdrawn by the registrant or until EPA has cause to suspend or cancel the registration as part of the Re-registration Program or an adverse finding by EPA. Since the average period of marketability of a pesticide ranges from 15 to 30 years, the PRA-imposed guideline indicating that data, other than health, medical, or tax records need not be retained for more than three years generally will be exceeded in this program.

The Agency will solicit packaging manufacturers to voluntarily certify and submit samples of CRPs, identify the manufacturer, identify whether the packaging is Younger Adult Use Effective (YAUE) or Senior Adult Use Effective (SAUE), and list the package's classification according to American Society for Testing and Materials (ASTM) Standard D3475, "ASTM Standard for Classification of Child-Resistant Packages." The Agency will compile the information into a book on CRP in the marketplace. The book would include photographs of the package, with each package classified according to the ASTM D3475 Standard. The Agency believes the book will provide a service to CRP manufacturers and pesticide registrants by displaying the various types of CRP in the marketplace which, in turn, should facilitate compliance with the CRP regulations. The Agency published a similar book in 1985 and believes that an updated version is necessary. Based on the Office of Management and Budget (OMB) PRA regulations codified in the CFR, EPA believes that the information to be solicited and compiled as such is not a information collection as defined in the OMB regulations at 5 CFR 1320(h)(1), and therefore no burden hours need to be reported for this activity.

3(f). Confidentiality

Although submission of confidential information is not required as a part of this information collection, there has been at least one instance where confidential data have been submitted voluntarily as supporting material for an exemption request from CRP compliance requirements.

When any trade secret or Confidential Business Information (CBI) is provided to EPA, such information is protected from disclosure under section 10 of FIFRA. Data submitted to EPA is handled strictly in accordance with the provisions of the FIFRA Confidential Business Information Manual.

This manual contains instructions relative to all contact with confidential documents, including responsibilities of EPA employees, physical security measures, CBI copying and destruction procedures, transfer of CBI materials within the EPA, to contractors or other government offices, computer security, CBI typing procedures (documents to be typed internally or on contract), and division internal procedures.

The manual dictates that all CBI must be marked or flagged as such, only authorized EPA personnel may be permitted access to CBI, and CBI must be kept in secure (double locked) areas. Additionally, CBI for destruction must be cleared by a Document Control Officer and Placed in the Office of Prevention, Pesticides and Toxic Substances paper shredder.

3(g). Sensitive Questions

Not applicable. No information of a sensitive or private nature is requested in this information collection activity.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a). Respondents/NAICS Codes

The North American Industrial Classification System (NAICS) code for respondents under this ICR is 325320 (Pesticide and other Agricultural Chemical Manufacturing).

4(b). Information Requested

Pesticide registrants subject to the regulations are required to certify to the Agency that the packaging for the pesticide product meets the standards of 40 CFR 157, or request an exemption to the requirement.

(i) Data items, including record keeping requirements

The respondent certification letter must exercise one of the following information options in this section or in section (i)(a) to comply with 40 CFR Part 157:

Certify to CRP by letter to Agency	The name, and EPA registration number of the product to which the certification applies, the Certification statement, the registrant's name and address, the date, and the name, title and signature of the company officer making the certification. The Certification statement must contain a statement that the pesticide product complies with 40 CFR 157.32, requirements including the revised effectiveness standards in 16 CFR 1700.15(b), when tested by the revised protocol testing procedures in 16 CFR 1700.20. A description of the packaging used and the ASTM Standard D3475-95, "Standard Classification of Child-Resistant Packages," designation is requested (not required).
Not meet Toxicity Criteria	Submit toxicity data that indicate a specific product's minimal toxicity, or reformulate to a less toxic product and assert that the CRP regulations do not apply. Approximately 1 percent of pesticide registrants choose this option for complying with the CRP program.
Not for Residential Use	Revise product labeling so that CRP regulations do not apply, i.e., specifying non-residential use areas, or eliminate residential use. The registrant is required to send EPA a copy of the revised labeling. Approximately 1 percent of pesticide registrants use this option. The cost/burden impact of this option is negligible and as such is not included in calculations.

Approximately 76 percent of pesticide registrants choose to certify that their pesticide product packaging meets the effectiveness, compatibility, and durability standards at 40 CFR 157.32. Registrants who certify are required to maintain data to corroborate the certification for the duration of the pesticide's registration as required by 40 CFR 157.36. Of those registrants who do certify, approximately 15 percent must submit data because of human safety/health risk concerns. If data is needed, EPA requests that registrants submit data electronically to expedite data analysis. Pesticide Regulation (PR) Notice 97-9 describes the benefits and requirements of electronic data submission (see attachment B).

(i)(a) Exemptions from CRP

Currently, registrants have several options by which they may be exempted from CRP requirements. These options include:

(1) Package the product in a large size so that CRP regulations do not apply. Exercising this option effectively eliminates sales to the general public. It is based on the concept that certain bulk size pesticide packages are intended for commercial use even in residential areas (i.e.,

exterminator use insecticides and contract lawn care products). These package sizes are specified in 40 CFR 157.24 (a)(2). The pesticide registrant is not required to seek a formal exemption for this option, and approximately 22 percent of registrants use this option. However, CRP may be required for products packaged in a size exceeding those outlined in exemption criteria at 40 CFR 157.24(a)(2) if it is determined by the EPA that the product is distributed or sold to the general public. As such, EPA expects that some of these registrants will no longer meet the criteria for the exemption.

(2) Registrants may also assert that an exemption to CRP is warranted because the hazards indicated by the toxicity criteria are not indicative of risk to humans, or that CRP is not technically feasible, practicable, or appropriate. Each request for an exemption is unique, and the data necessary to support an exemption are unique. Approximately 1 percent of pesticide registrants choose this option with the CRP program.

(ii) Respondent Activities

In order to comply with the CRP regulations, registrants must engage in the following activities:

Read instructions	Review requirements of FIFRA section 25 (c)(3) and 40 CFR Part 157, including its reference to 16 CFR 1700.15(b) and 16 CFR 1700.20;
Plan activities	Decide under which option to comply with CRP compliance requirements or whether an exemption will be requested;
Create information	Compile necessary data regarding compliance or exemption from CRP requirements;
Review data for reliability and appropriateness	Review performance testing data to ensure that it will support CRP certification and identify the ASTM Standard D3475-95, the Standard Classification of Child-Resistant Packages for the package.
Prepare and submit certification statement.	Draft a certification statement citing compliance with CRP requirements and include a description of the package, or explain why the product is not subject to CRP, or request an exemption from CRP compliance requirements and compile/cite any supporting data as necessary. Submit information to EPA.
Store, file, and maintain data	Maintain any data and information sent to EPA to certify CRP compliance, support a determination as to why product is not subject to CRP, or justify an exemption from CRP.

5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a). Agency Activities

Upon receipt of a certification letter, EPA preforms the following activities:

Review correspondence	Review correspondence for completeness. Incomplete/incorrect certifications are returned to registrants;
Evaluate data and advise registrant	Evaluate data submitted and determine whether the registrant has met the CRP requirements, has sufficiently substantiated reasons for not being subject to CRP (e.g. reformulate to a less toxic product) or decide whether or not to grant an exemption. Advise registrant of decision;
Store, file, and maintain data	All CRP data submitted to the Agency are filed in the registration file jacket for the pesticide product. The Agency maintains a database of all CRP certifications which identifies for each pesticide product, the CRP, the status of CRP compliance, the date of certification, and the type of package.

5(b). Collection Methodology

EPA only collects data in support of a CRP certification when there are human safety/health risk concerns. EPA requires that registrants maintain data in support of their certifications of the child-resistance of the product's packaging or devices. At the time of CRP certification we are requesting that the registrant identify the type of packaging used. This data is a part of their recordkeeping requirements (under 40 CFR 157.36). This additional piece of data will enable the Agency to contact all pesticide registrants using a particular type of CRP should a generic problem with the CRP become evident. It will also facilitate the review of CRP exemption requests because the Agency can ascertain how similar pesticide formulations are packaged.

The generic database system continually tracks all registration actions from the registration-pending stage through to full registration and until a product is canceled. A generic database maintains information on both currently registered products and previously registered products, thereby acting as a registration action historical file. Additionally, the CRP compliance certification hard copy correspondence letters are filed in the pesticide product registration jacket file room.

5(c). Small Entity Flexibility

The incorporation of alternative methods to verify that the package meets the requirements of 40 CFR 157.32 have allowed manufacturers to use extrapolation schemes, available child-resistant protocol test data, and supporting documentation without spending the time and money to develop the data on their exact package. The burden and cost to industry also is minimized by: the reference of the CPSC effectiveness standards and protocol test procedures that preclude duplicative testing for pesticidal and non-pesticidal purposes, and also allow for the use of CRP developed for non-pesticidal purposes; the use of packaging manufacturer's data rather than product-specific data; discretion and innovation with regard to product packaging compatibility and package selection; and the granting of the size exemptions without requiring an application from the registrant or approval by EPA.

5(d). Collection Schedule

CRP certification is usually conducted only when a registrant notifies EPA by application of their intention to either change packaging, enter the residential market, or otherwise become subject to CRP regulations.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a). Estimating Respondent Burden

The total estimated respondent burden to comply with this information collection activity is 853.4 burden hours/year at a burden cost of $58,232.00. This estimate is based on the following analysis:

The respondent burden is based on 502 registrants with a burden of 1.7 hours each per response. The number of registrants is based on the number of active Child-Resistant Packaging (CRP) registrations in FY99 (921 CRP registrations). The CRP recertification response to PR Notice 96-2 over a 23 month period demonstrated the fact that annually 55% of CRP registrations interact with the Agency. No management time is involved in the respondent burden because CRP is generally handled by the technical personnel such as the regulatory affairs person and packaging personnel with some clerical support. Clerical support is a fairly recent development to lessen the technical burden. This change was made possible by PR Notices 96-2 and 97-9 which clarified CRP certification procedures and data requirements so that some of the burden could be delegated from technical personnel to clerical personnel. The 1.7 hour response burden is based on an average response time for respondents submitting CRP certifications, CRP certifications with data, exempt from CRP based on large package size, and exempt from CRP due to a lack of toxicity, packaging issues, eliminating residential use, lower product toxicity. These CRP actions result in 1 hour technical time and 0.7 clerical time, which is broken down to: 6 technical minutes to ascertain whether the product is subject to the CRP regulations (meets toxicity criteria, residential use); 6 technical minutes to decide whether to submit a CRP certification, data, be

exempt from regulations due to large size or other criteria; 30 technical minutes to create/prepare the information; 12 clerical minutes to format submission and create/prepare information; 6 technical minutes to review submission for accuracy and appropriateness; 12 technical minutes to sign the appropriate documents; and 30 clerical minutes to mail the submission, file the respondent copy and CRP documentation.

The 1.7 hour response burden is based on an average response time for 69% of respondents submitting CRP certifications, 15% of respondents submitting CRP certifications with data, 13% of respondents exempt from CRP based on large package size, and 3% of respondents exempt from CRP due to a lack of toxicity, packaging issues, eliminating residential use, lower product toxicity. The percentage of various responses is based on the type of CRP submissions received annually. The 69% (346) of respondents submitting CRP certifications require 1 hour of technical time: determine the product is subject to the CRP regulations (meets toxicity criteria, residential use); identify the type of CRP used; prepare the CRP certification; and 0.5 hour of clerical time to complete the CRP certification submission to the Agency and file the supporting CRP data. The 15% (76) of respondents submitting CRP certifications with data require 2 hours of technical time: determine the product is subject to the CRP regulations (meets toxicity criteria, residential use); identify the type of CRP used; prepare the CRP certification; gather the supporting CRP data; and 2 hours of clerical time to prepare the CRP data package, complete the CRP certification submission to the Agency, and file the supporting CRP data. The 13% (66) of respondents exempt from CRP based on large package size require no time because the CRP regulations require no action on their part. The 3% (14) of respondents exempt from CRP due to a lack of toxicity, packaging issues, eliminating residential use, lower product toxicity require 1.6 technical hours and 0.4 clerical hours to prepare their submission indicating why CRP is not required and/or CRP is not possible. This results in the chart below.

Type of Response	**# Respondent**	**Technical Burden**		**Clerical Burden**		**Aggregate Burden**
		Hours Per Event	**Total**	**Hours Per Event**	**Total**	
CRP certification	346	1	346	0.5	173	519
CRP certification with data	76	2	152	2	152	304
Exempt from CRP due to large package size	66	0	0	0	0	0
Exempt from CRP due to lack toxicity, packaging, no residential use, lower product toxicity	14	1.6	22.4	0.4	5.6	28
TOTAL	502	–	520.4	–	330.6	851

6(b). Estimating Respondent Costs

The total average cost of the estimated burden per respondent to comply with the CRP is approximately $116.00 per response. Respondent costs are based on technical/managerial and clerical burden hours estimated at $88 and $40 per hour, respectively. The price per hour increase is based on current labor rates as supplied by the Bureau of Labor Statistics, and represent loaded labor rates, i.e., salary and overhead costs. There are no capital expenditures associated with this information collection activity.

ANNUAL RESPONDENT BURDEN/COST ESTIMATES

COLLECTION ACTIVITIES	**Burden Hours**		**TOTAL**	
	Tech. $88/hr.	**Clerical $40/hr.**	**Hours**	**Costs**
Read instructions	0.1	0	0.1	8.80
Plan activities	0.1	0	0.1	8.80
Create information including electronic format of data	0.5	0.2	0.7	52.00
Process, compile, and complete written compliance document	0.1	0	0.1	8..80
Review submission	0.2	0	0.2	17.60
Store, submit, file, or maintain data	0	0.5	0.5	20.00
TOTAL	1.0	0.7	1.7	116.00

ANNUAL BURDEN: 1.7 Total Hours x 502 Respondents = 853.4 Burden Hours

ANNUAL COSTS

(a) Technical: 1.0 hours x $88 x 502 respondents = $44,176.00
(b) Clerical: 0.7 hours x $40 x 502 respondents = $14,056.00
Total $58,232.00

6(c). Estimating Agency Burden and Cost

The Agency burden hours for the entire CRP process will increase from 3.9 hours to 7.4 hours per response. Based on human safety/health risk concerns there has been an increase in review of data connected with the CRP certifications and human safety/health risk concerns potentially may cause a revocation of the large size exemption for nonliquid swimming pool chemicals leading an increase in the number of CRP certifications. Additionally, there is an increase in CRP certifications based on a larger percentage of registrants changing their packages due to cost, recycling concerns, and safety or electing CRP certification rather than comply by a

more time consuming option (e.g. submitting toxicity data, reformulate to a less toxic product, or requesting an exemption).

Annual burden to the Agency is estimated at 3714.8 burden hours at a cost of $245,176.80. The main portion of the burden hours per response is expected to result from the evaluation of data related to human safety/health risk concerns associated with CRP certification, and assessing some of the more complex options for compliance (e.g. submitting toxicity data or requesting an exemption).

Total cost per response to comply with the CRP is estimated at approximately 7.4 hours costing $488.40 per response.

ANNUAL AGENCY BURDEN/COST ESTIMATES

COLLECTION ACTIVITIES	**BURDEN HOURS (per respondent)**			**TOTAL**	
	Mgmt. $96/hr.	**Tech. $70/hr.**	**Clerical $33/hr.**	**Hours**	**Costs**
Read correspondence	0	0.6	0	0.6	$42.00
Execute activities including data review and certifications for large size nonliquid pool chemicals	0	6	0	6	$420.00
Store, file, or maintain data	0	0	0.8	0.8	$26.40
TOTAL	0	6.6	0.8	7.4	$488.40

ANNUAL BURDEN: 7.4 Total Hours x 502 Respondents = 3714.8 Hours

ANNUAL COSTS

(a) Technical: 6.6 hours x $70 x 502 respondents = $231,924.00
(b) Clerical: 0.8 hours x $33 x 502 respondents = $13,252.80
Total $245,176.80

6(d). Bottom Line Burden Hours and Cost Tables

MASTER TABLE

	Hours	Costs
Respondent: Burden/Cost Estimates	853.4	$58,232.00
Agency: Burden Cost Estimates	3714.8	$245,176.80

6(e). Reasons For Change In Burden

There is a slight increase in the number of respondents from 449 to 502 from the last ICR approval. However, the total burden hours per respondent for compliance with the CRP requirements will remain the same, 1.7 hours at a cost of $116.00 per response. The estimated annual burden under the last ICR approval was 763.3 hours. Under this renewal ICR, the estimated annual burden to be 853.4 hours. The increased burden represents an adjustment to the Agency's burden estimate for this renewal ICR that corresponds with the increased number of registrants electing to certify to the CRP requirements. A number of registrants who have traditionally marketed their products for the nonresidential market have decided to enter the residential market triggering the CRP requirements. Respondents may be opting to certify to CRP due to changes in the cost of packaging, recycling, and safety factors. Some registrants voluntarily use CRP to avoid having to stock multiple packaging inventories for different products and/or an increased environmental conscience. Some respondents may be electing to certify to CRP because it is less time consuming than electing to submit toxicity data, reformulate to a less toxic product, or request an exemption.

6(f). Burden Statement

The annual "respondent" (certifier) burden for the Compliance Requirement for the CRP regulations is estimated to average 1.7 hours per submission of data necessary to support a claim that product is not subject to CRP, should be exempt from CRP, or CRP certification, including time for: reading relevant federal legislation and regulations; conducting performance testing on closures and/or devices; reviewing test data; prepare submission or CRP certification; and recordkeeping regarding the CRP certification or submission. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460.; Include the OMB control number in any correspondence, but do not submit the requested information or forms to this address. The requested information should be submitted in accordance with the instructions in the Federal Register Notice seeking comment on this ICR. Please reference this document by the OMB Control No. 2070-0052 in all correspondence.

Attachments to the Supporting Statement

Attachment A:	Section 25 (c)(3) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
Attachment B:	Pesticide Registration Notice 97-9
Attachment C:	40 CFR Part 157 - Packaging Requirements for Pesticides and Devices